

Biologicals and Export Controls

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Department of Commerce Export Controls



- Dual-use biological material
 - subject to BIS regulatory jurisdiction
 - predominantly commercial/academic uses
 - could also be used in military applications
 - Listed in Export Administration Regulations (EAR) by Export Control Classification Number (ECCN)
 - Commerce Control List (CCL)
- May require export license
 - Based on multilateral regimes (Australia Group)
 - Unilateral (Select Agents not on the AG list, vaccines)
- Other Controls to consider – USML (CAT XIV), OFAC

Department of Commerce Export Controls



- Part 732 of the EAR – Steps for using the EAR
 - What is the item
 - Where is it going (what country)
 - Who will use it (ultimate consignee, end users)
 - What will they do with it (end use)
 - What else do the recipients do (red flags)
- Supplements 1 -3 of Part 732 of the EAR
 - Decision Tree for need for export license
 - Decision Tree for subject to the EAR
 - Know your Customer Guidance

Export Checklist



- Is it under Commerce Control ?
 - Commodity Jurisdiction if unsure (DDTC - STATE)
- What is the ECCN of the item to be exported?
 - Commodity Classification if unsure (DOC)
 - EAR99 usually No License Required (NLR)
 - Specific ECCN – may result in
 - License required
 - No License Required
 - License exception eligible

What May Require a License?



- Biological agents and genetic elements (1C351,1C353,1C354) (Australia Group list plus Select Agents)(worldwide)
- Vaccines (ECCN 1C991) (limited destinations)
- Biological processing equipment (ECCN 2B352)
- Technology (Development, Production, Use)
 - ECCN 1E001, 2E001, 2E002, 2E301
- Foreign worker in US facility (deemed export)
- Re-exports

Technology Considerations



- Is the technology for controlled biological processing equipment?
 - “Development”
 - “Production”
 - “Use”
- Is the technology related to manipulation of controlled biologicals that is not public domain or fundamental research?
- Where is the transfer taking place?
 - Deemed export vs. tech transfer

Relevant License Exceptions



- GOV (Government) EAR 740.11
 - Agencies of Cooperating Governments
 - Country Group A:1 (see Supplement No. 1 to 740) and the national governments of Hong Kong, Singapore, and Taiwan
- STA (Strategic Trade Authority) EAR 740.20
 - Certain Toxins from ECCN 1C351
 - Has reporting requirements
 - Less than 100 mg, six or fewer shipments per CY
- Read regulations carefully before use

Biological Agents and Toxins



- 1C351 and 1C354
 - Human, Animal and Plant Pathogens Australia Group (AG) controlled -
 - Select Agents not on the AG list
 - Select Agent (SA) exempt strains ARE controlled for export
- 1C353
 - Genetic Elements for controlled agents/toxins
- 1C991
 - Vaccines
 - Medical toxins

Genomic Material



Genetic elements include and not limited to

Chromosomes

Genomes

Plasmids

Transposons

Vectors

May be genetically modified or unmodified

May be synthesized



Current Control Language for Genetic Elements and Genetically-Modified Organisms:

- Genetic elements that contain nucleic acid sequences **associated with the pathogenicity** of any of the microorganisms in the list.
- Genetic elements that contain nucleic acid sequences coding for any of the toxins in the list, or for their sub-units.
- Genetically-modified organisms that contain nucleic acid sequences **associated with the pathogenicity** of any of the microorganisms in the list.
- Genetically-modified organisms that contain nucleic acid sequences coding for any of the toxins in the list or for their sub-units.

Genetic Elements and Genetically-Modified Organisms Technical note excerpt



Technical note:

Nucleic acid sequences **associated with the pathogenicity** of any of the micro-organisms in the list means any sequence specific to the relevant listed micro-organism:

- that in itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health; or;
- that is known to enhance the ability of a listed micro-organism, or any other organism into which it may be inserted or otherwise integrated, to cause serious harm to human, animal or plant health.

Genetic Elements



- Whole Nucleic acids – not controlled if
 - Certified non-infective and chemically treated to be non-recoverable
- Chimeric Viruses- controlled if
 - Based on a controlled virus
 - Has controlled virus element in non-controlled virus
- Plasmids - controlled if
 - Promoter present
 - Complete gene or Viral Particle
 - Replication competent

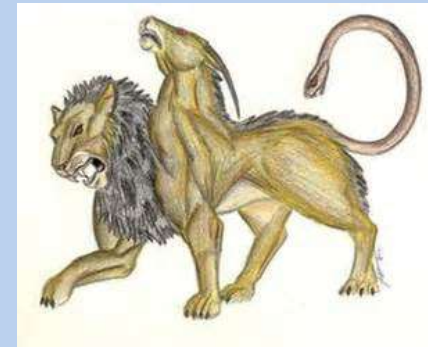
Example: Chimeric Viruses



Ebolavirus



**Genetically modified Vesicular stomatitis virus
(controlled as genetically modified VSV)**

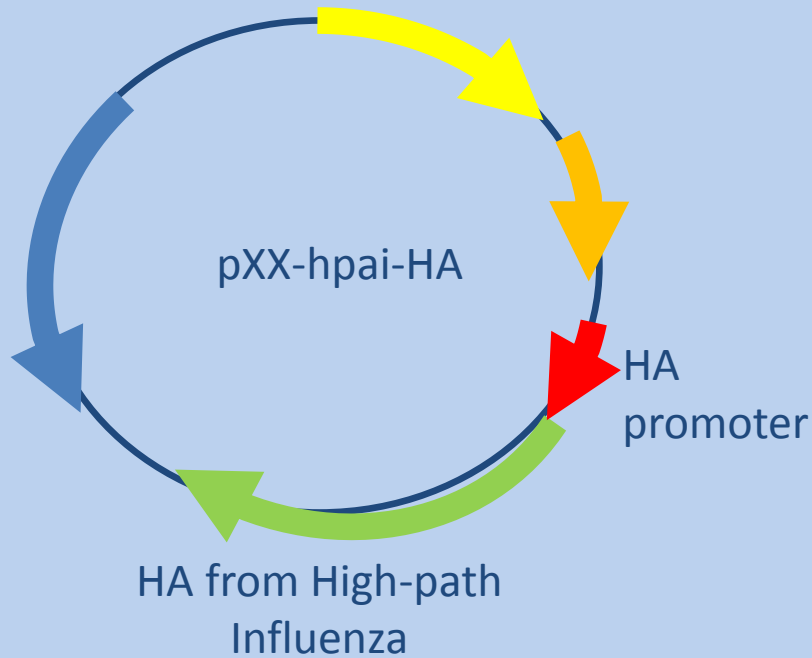


If the ebolavirus GP were incorporated into a non-controlled virus, this would be still controlled as a genetic element.

Example: Plasmids

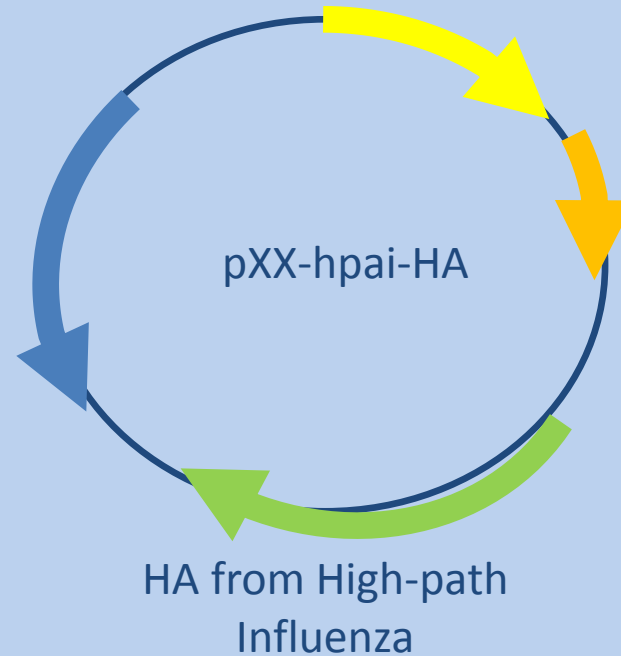


Expression plasmid + promoter – Controlled



HA + promoter = complete gene (viral particle replication competent)

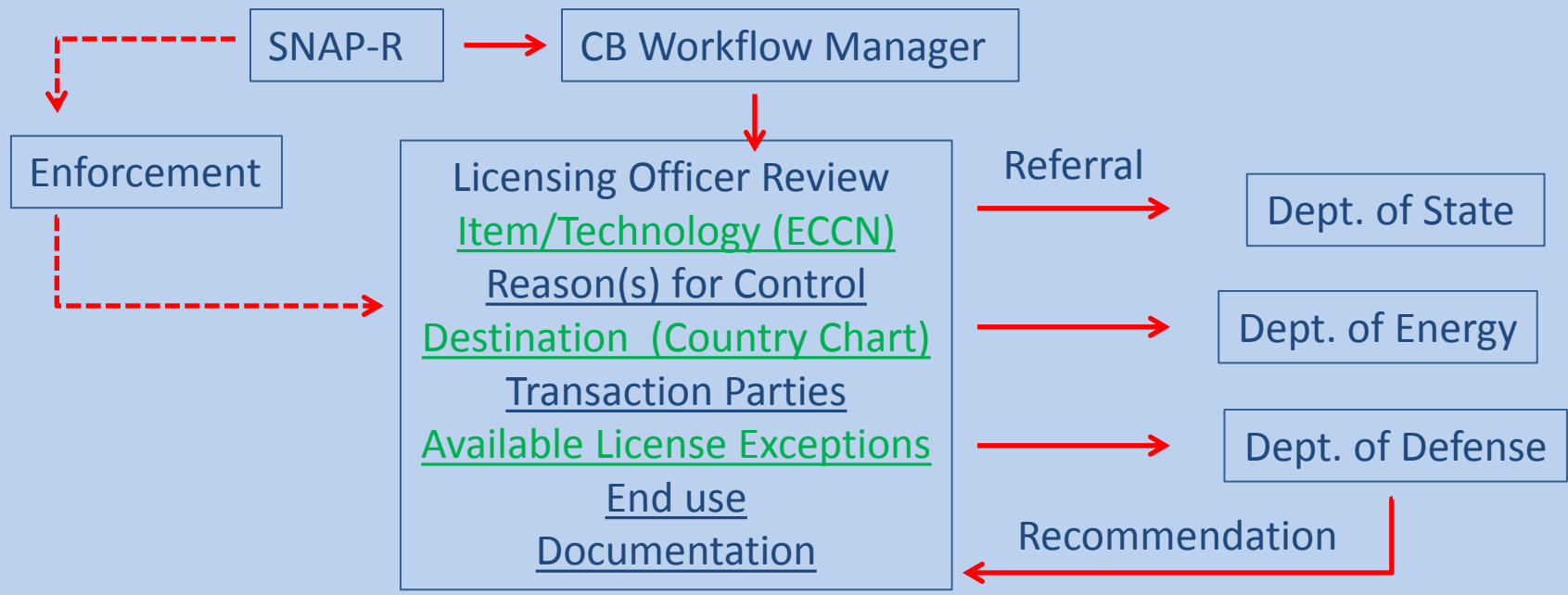
Expression plasmid – Not Controlled



Without the promoter, the element is not replication competent



License Application Review



Return without Action (RWA) at any point



Validated License (or denial)

Export Controls

Guide to Success



- Don't forget Select Agent exempt material may need license
(List specific strain , serotype, BSL, and quantity)
- ECCNS (1C351,1C353,1C354) agents/toxins need license worldwide including Canada
- Recipient laboratory is ultimate consignee/end user
- Provide info on researcher, end use and biosafety level capability in additional information
- Provide shipment amounts in mg, ml, etc. and cost (\geq \$1)
- Highlight any DURC or GOF activity
- Vaccine seed stock is not considered vaccine
- If technology transfer
 - List all ECCNS
 - Clarify deemed versus regular export
 - Cost \geq \$1

Technology for Dual Use



“Development” is related to all stages prior to serial production, such as: design, design research, design analyses, design concepts, assembly and testing of prototypes, pilot production schemes, design data, process of transforming design data into a product, configuration design, integration design, layouts.

Production



“Production” means all production stages, such as: product engineering, manufacture, integration, assembly (mounting), inspection, testing, quality assurance.

Use



“Use” includes all of the following:

- Operation, installation (including on-site installation), maintenance (checking), repair, overhaul and refurbishing
- Definition of “Use” differs for 600 series items

Technology Considerations



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 - “Development”
 - “Production”
 - “Use”
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- Where is the transfer taking place?
 - Deemed export vs. tech transfer
- Consider Fundamental Research, Public Domain

Technology NOT Subject to the EAR



- Publicly Available Technology and Software
- Already published or will be published (734.7)
- Arise during fundamental research (734.8)
- Included in certain patent applications (734.10)
- Review 734 for recent changes September 2016

Fundamental Research (EAR 734.8)



University based research

Research based at federal agencies

Corporate Research

“Fundamental research means research in science, engineering, or mathematics, the results of which ordinarily are published and shared broadly within the research community, and for which the researchers have not accepted restrictions for proprietary or national security reasons “

Deemed Export (734.13)



Export or Re-Export of Technology or Software
release in the U.S. of technology or software to a foreign national

Release

“Release” of technology or source code, subject to the EAR to foreign persons in the U.S., or in a third country, through:

Visual inspection of U.S. origin equipment and facilities

Oral exchanges of information in the U.S. or abroad

Application of personal knowledge or technical experience acquired in the U.S. to situations that will benefit



Deemed Key Points

- Two Triggers must be met
- Technology must require a license
 - Rule in/out fundamental research and public domain
 - First identify the ECCN of the technology
 - See where a license would be required
 - If license is needed evaluate foreign national
- Foreign National background
 - No license needed
 - Green card, protected person
 - Export to home country would not require a license
- Apply for a deemed export license when
 - Technology license needed to FN home country

Scenarios



- Researcher working with Suid Herpesvirus 1 (Pseudorabies)
- Is this a Select Agent? No
- CCL listed pathogen? Yes (Australia Group)
- Export License for virus shipment required ?Yes (all countries)
- Deemed export ? Only if FN is learning controlled technology

Scenarios



- Researcher working with Rift Valley Fever Virus
- Is this a Select Agent? Yes
- CCL listed pathogen? Yes
- Exports strain to colleague in Kenya for use in vaccine production ?? License Required
- Foreign student in lab on different project
 - not working with pathogens ??? No
 - working with pathogen?? Maybe
- Research generates an attenuated strain
- no approval or IND # so License required for export

Scenarios



- Research generates an attenuated strain of RVFV
 - no approval or IND # yet
 - Still ECCN 1C351 and export license required
- FN growing virus using published methods
 - Public domain tech, no deemed export
- FN Research shifts to novel methods of growing virus
 - Deemed export license and/or
 - Commodity Classification to rule on fundamental research exception

Contact Info



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<https://www.bis.doc.gov/index.php/policy-guidance/product-guidance/chemical-and-biological-controls>

<https://www.export.gov/welcome>

Website Shortcuts



A screenshot of the BIS website homepage. The browser address bar shows "US Department of Commerce [US] | https://www.bis.doc.gov". The navigation menu includes Home, About BIS, Regulations, Licensing, Enforcement, Compliance & Training, Policy Guidance, Add'l Programs, Reform, and Data. The main content area features a large banner for "Export Administration Regulations" with a sub-header "Amendments to the Export Administration Regulations; Update of Arms Embargoes on Cote d'Ivoire, Liberia, Sri Lanka and Vietnam, and Recognition of India as Member of the Missile Technology Control Regime". To the right, there are three news items: "Amendments to the Export Administration Regulations: Update of Arms Embargoes on Cote d'Ivoire, Liberia, Sri Lanka and Vietnam, and Recognition of India as Member of the Missile Technology Control Regime", "TWO MEN SENTENCED IN SCAM TO ILLEGALLY EXPORT GOODS TO SYRIA", and "Update 2016 Conference on Export Controls and Policy". Below the banner, there are six widget boxes: "Would you like to..." (circled in blue), "Export Control Reform" (with an ECR icon), "Consolidated Screening List" (with a sigma icon and circled in black), "Exporter Portal" (with a shield icon and circled in red), "In The News" (with a BIS News icon), and "Report Violations" (with a seal icon).

